

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

Charm SL (raw bovine and caprine) and SL-6 (raw bovine)  
Beta-Lactam Tests

GENERAL REQUIREMENTS

1. See Appendix N General Requirements form items 1-8 & 13 \_\_\_\_\_

SAMPLES

2. See Appendix N General Requirements (GR) form item 9 \_\_\_\_\_

APPARATUS & REAGENTS

3. Equipment \_\_\_\_\_

- a. Strip Incubator,  $56 \pm 1^{\circ}\text{C}$  SL Beta-lactam test;  
 $45 \pm 2^{\circ}\text{C}$  SL-6 Beta-lactam Test \_\_\_\_\_

1. Level. Temperature checked daily (day of use),  
records maintained \_\_\_\_\_

2. Thermometer, for each incubator (App N GR #3) \_\_\_\_\_

3. Lid closed (spring ajar), when not running tests \_\_\_\_\_

4. Incubator Temperature: \_\_\_\_\_

- b. ROSA Reader or equivalent with print out or download  
of data. ROSA Reader V1.07 or higher for SL-6, or  
equivalent capable of reading 3 line test,  
Manual Available Serial Number: \_\_\_\_\_

1. Calibrators - 2 for each assay- 2 lines for SLBL  
and/or 3 lines for SL-6. \_\_\_\_\_

Range(s)

Two Line:

Low: \_\_\_\_\_

High: \_\_\_\_\_

Three Line:

Low: \_\_\_\_\_

High: \_\_\_\_\_

- 2. Calibrator serial numbers match ROSA reader SN \_\_\_\_\_
- 3. **Do not proceed if out of range.** Manufacturer should be contacted for corrective actions \_\_\_\_\_
- 4. Printer or computer link for hardcopy download \_\_\_\_\_
- 5. Records maintained \_\_\_\_\_
- c. Pipettor- 300 µL and disposable tips, calibrated (see App. N GR item 7) \_\_\_\_\_
- d. Or single use 300 µL poly-pipet with overflow bulb to accurately measure amount of sample, supplied by manufacturer **(screening only)** \_\_\_\_\_
- e. Optional Timer - if not built into Incubator \_\_\_\_\_
- f. Optional Centrifuge (Not applicable to SL-6 Beta-lactam Test)- mini or equivalent (1200-2000 x g) for frozen controls \_\_\_\_\_

#### 4. Reagents

- a. Test Strips \_\_\_\_\_  
Lot #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
Rec'd: \_\_\_\_\_ QC Date: \_\_\_\_\_ by \_\_\_\_\_
- b. Positive Control \_\_\_\_\_
  - 1. Lyophilized or tablet 5 ppb Penicillin G for SL Beta-lactam Test \_\_\_\_\_  
Lot #: \_\_\_\_\_ Exp Date: \_\_\_\_\_
  - 2. Lyophilized or tablet 5ppb Penicillin G/10ppb cloxacillin for SL-6 Beta-lactam Test \_\_\_\_\_  
Lot # \_\_\_\_\_ Exp. Date: \_\_\_\_\_
- c. Negative Control -
  - 1. Previously negative tested raw milk (item 5b) \_\_\_\_\_

## 5. Reagent stability

- a. SL-6 reagents received refrigerated.
- b. Reagents stored at 0-4.4°C, maintain no longer than manufacturer's expiration date
- c. Negative Control - raw milk tested -600 or more negative with SL Beta-lactam Test or -400 or more negative with SL-6 Beta-lactam

Test Value:\_\_\_\_\_ **Do not proceed if out of range.**

- 1. Used within 72 hours when maintained at 0-4.4°C
- 2. Test for suitability each time, records maintained
- 3. Or, frozen immediately (within 6 hours) and stored in a non-frost-free freezer, or in a styrofoam container in a frost free freezer, for no more than 2 months at -15°C or below

Lab Date prep:\_\_\_\_\_ Lab Exp. Date: \_\_\_\_\_

- a. For SLBL **ONLY**, not applicable to SL-6 thaw, centrifuge 3 minutes, cool and use within 24 hours. Do not refreeze.
- d. Positive Control- Manufacturer supplied, maintain no longer than manufacturer's expiration date
- 1. Reconstituted with Negative Control (raw milk), used within 48 hours when maintained at 0-4.4°C
- 2. Test for suitability each time prepared and/or day of use, must produce +400 or greater reading, records maintained.

Test Value:\_\_\_\_\_ **Do not proceed if out of range.**

- 3. Or, frozen immediately (within 6 hours) and stored in a non-frost-free freezer, or in a styrofoam container in a frost-free freezer, for no more than 2 months at -15°C or below

Lab Date prep: \_\_\_\_\_ Lab Exp. Date: \_\_\_\_\_

- a. Thaw, centrifuge 3 minutes( not applicable to SL-6 Beta-lactam Test), cool and use within 24 hours. Do not refreeze.

#### TECHNIQUE

#### 6. Daily Performance and Operation Check

- a. See App. N GR item 10)
- b. Reader Versions 1.5 and higher, use Escape 5 reader function to enter performance monitor mode of reader-reference manual for directions
- c. Check Calibrators, records maintained
- d. Controls give appropriate readings in performance monitoring mode (reader version 1.05 and higher) prior to any sample analysis. If out of range, manufacturer should be contacted for corrective action, 800-343-2170.
- e. Do not proceed if out of range.

#### 7. Test Procedure

- a. Label Test Strips, one for each test sample and each control
- b. Place strip into appropriate incubator, avoid crushing sample compartment. For multiple samples, complete steps b-f for each sample/control, before starting test of next sample.
- c. While holding strip flat, peel (to 'peel to here' line) back plastic to expose sample pad compartment
- d. Mix milk sample or control 25 times in seven seconds with a 1 ft movement or vortex control for 10 seconds when appropriate

- e. Slowly pipette 300 µL sample to either side of the sample pad compartment(if applicable, use etched line on incubator as location guide). Avoid contact of sponge with pipet tip. \_\_\_\_\_
- 1. Draw up sample, avoiding foam and bubbles.(with 300ul calibrated pipet only pre-wet tip by expelling sample and drawing up again) \_\_\_\_\_
- 2. Or for **Screening only** use poly pipet \_\_\_\_\_
  - a. While holding poly pipet almost vertically with bulb side pointing down, depress top bulb and insert into sample (below foam). \_\_\_\_\_
  - b. Release bulb and sample should completely fill pipet shaft and overflow into bottom ½ of lower bulb \_\_\_\_\_
  - c. Pipet sample in pipet shaft by depressing top bulb only into test strip while leaving excess sample in overflow bulb \_\_\_\_\_
- f. Re-seal plastic firmly around sample pad compartment \_\_\_\_\_
- g. Repeat Step 7b-f for each sample and/or control test strip in incubator \_\_\_\_\_
- h. Close and latch incubator cover. If no automatic timer in incubator, set timer for 8 minutes, do not exceed 10 minutes \_\_\_\_\_
- i. At end of incubation, visually inspect C (Control) line, an absent C line or a partial C line or an indistinct C line indicates an invalid test and the sample/control must be re-tested \_\_\_\_\_
- j. Insert only valid test(s) in ROSA reader (set to appropriate channel). \_\_\_\_\_
  - 1. SLBL slow blink for SL Beta-lactam Test \_\_\_\_\_
  - 2. SLBL rapid Blink for SL-6 Beta-lactam Test \_\_\_\_\_

- k. Press ENTER, reading and interpretation appear in 5 seconds, read strips within 10 minutes of completion of incubation

**8. Interpretation with ROSA Reader**

- a. If there is a negative or zero reading on the reader, sample is **Negative (NF)**
- b. If there is a positive reading on the reader, sample is **an Initial Positive**

**9. Confirmation of Initial Positive Samples (see App. N GR item 11)**

**10. Reporting (see App. N GR item 12).**

- a. Reader tapes or computer print outs maintained